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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/811,014

03/26/2004

David G. Wild

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CONVATEC INC.

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EXAMINER

OSTRUP, CLINTON T

ART UNIT

PAPER NUMBER

3771

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/811,014	Applicant(s) WILD ET AL.	
	Examiner CLINTON OSTRUP	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/13/08 & 12/23/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7,8,10,11,14,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7,8,10,11,14,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 12/23/08 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 11/13/08 & 12/23/08 have been entered. As directed by the amendments, claim 1 has been amended and claims 4, 6, 9, 12-13 and 15-18 have been previously cancelled. Thus, claims 1-3, 5, 7, 8, 10, 11, 14, 19 and 20 are presently pending in this application.

Drawings

2. The drawings are objected to because in figure 1, one of the controllers is not labeled. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: on page 3, at the end of the first full paragraph, there are two periods.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 5, 7-8, 10-11,14 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barak (6,494,852) in view of Taheri (4,624,244).

Barak discloses a compression device for the limb of a mobile patient (fig. 1) comprising: an inflatable sleeve 1 (fig.2) adapted to surround the limb; a conduit 4 attached to said sleeve for delivering fluid to said sleeve; and a portable, wearable controller 3 (fig. 1) or control unit 68 (col. 6, lines 63-67) attached to said conduit that generates and controls the flow of fluid in the device; wherein the sleeve includes a leg cuff and a foot cuff (fig. 2); the leg cuff has three cells on the lower sleeve including: a gaiter cell 2 adapted to wrap around the lower limb in the region closest to the ankle, a

mid-calf cell 2 adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell 2 adapted to wrap around the lower limb in the region between the mid-calf cell and the knee (best seen in fig. 2), except that it does not explicitly disclose that the sleeve includes consists of a leg cuff and a foot cuff and the leg cuff consists of only three cells and each cell consisting of only one compartment..

However, Barak teaches that “the invention is also intended for use on any body limb such as a foot, a part of a leg” (col. 4, lines 14-15) and “the number of cells in the sleeve can vary, according to the desired treatment” (col. 10, lines 34-35).

Taheri teaches a similar compression device having a sleeve with a leg cuff (27) and a foot cuff (11); the leg cuff consists of three cells: a gaiter cell (B) adapted to (partially) wrap around the lower limb in the region closest to the ankle, a mid-calf cell (C) adapted to (partially) wrap around the lower limb above the region occupied by the gaiter cell and an upper cell (D) adapted to (partially) wrap around the lower limb in the region between the mid-calf cell and the knee with each cell having only one compartment (bladders inside B, C, and D) for the treatment of diseased leg veins which result in venous hypertension. See: figures 1-3 & col. 1, lines 13-27.

Therefore it would have been obvious to one of ordinary skill in the art at the time of invention was made to limit the Barak device to include only a leg cuff and a foot cuff, as taught by Taheri, in order to obtain a device that could be used to treat the lower limb of a person having diseased leg veins.

Since Barak already teaches that “various changes, omissions to the form and detail thereof may be made therein” (col. 10, lines 38-40), and Taheri suggest forming a

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lower leg treatment device, it would have been obvious to one having ordinary skill in the art at the time the invention was made to eliminate the cell of the thigh, to form a lower leg treatment device. Moreover, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. In re Karlson, 136 USPQ 184.

Re claims 2-3, 5, 7, Barak discloses the controller comprises a microprocessor control system (control unit 68, col. 6, lines 63-67) and a pump (pump unit 60, col. 6, lines 22-33); wherein at least one pressure sensor 62/63 or pressure monitoring means (col. 6, lines 37-38) is associated with said sleeve ; wherein said sleeve is low profile and discrete (fig. 1); said leg and foot cuffs are anatomically shaped to provide compression on those parts of the leg or foot which have the greatest effect on blood flow (best seen in fig. 2).

Re claims 10-11 and 19, Barak discloses that the controller is battery operated (rechargeable battery pack 67, col. 6, lines 26-28); wherein each cell is monitored by a sensor 62/63 (col. 6, lines 37-38); and a method of preventing or treating edema or DVT (col. 2, lines 42-49) comprising applying a compression device of claim 1 to the limb of a mobile patient.

Re claims 8 and 20, Barak discloses the claimed inventions having all the features except for a sock interposed between the sleeve and the limb. Having a patient wear a sock, when using the device, would be obvious to a skilled artisan. A sock would prevent direct contact of the device with the patient's skin and would

therefore prevent direct contamination of the user's skin, and/or the transfer of bodily fluids to, or from, the user to the device. Moreover, a sock would help prevent skin irritation, skin shear and chaffing at the contact surface between the device and the skin of the limb during use.

Re claim 14, Barak discloses the claimed inventions having all the features except it is silent regarding the cells may be pressurized to the same or different predetermined pressures. However, Barak teaches (fig. 5) a pressure system 50 that has a range of pressure of 50-100 mmHg, and therefore it would have been obvious to one of ordinary skill in the art at the time of invention was made to operate the Bark's pressure system, such that the cells may be pressurized to the same or different predetermined pressures, for the purpose of providing a variety of compression therapy being applied on different body parts of the patient suitable to the patient's condition.

Response to Arguments

6. Applicant's arguments with respect to claims 1-3, 5, 7-8, 10-11, 14 and 19-20 have been considered but are moot in view of the new ground(s) of rejection. However, in order to expedite prosecution, they have been addressed as they read upon the cited prior art.

In response to applicant's argument that "Thus, from reading Barak, et al., one of ordinary skill in the art would believe that it is essential to pressurize the thigh in order to obtain benefit from that device", the examiner respectfully disagrees.

There is no evidence disclosed in Barak et al. to teach that the device would not work without the thigh cuff. Furthermore, since Barak already teaches that "the number

of cells in the sleeve can vary, according to the desired treatment" (col. 10, lines 34-35) and "various changes, omissions to the form and detail thereof may be made therein" (col. 10, lines 38-40), therefore there appears to be no unobviousness for Barak to apply pressure only to the foot and leg, especially in view of the teaching of Taheri, which clearly teaches a compression device having a sleeve consisted of a leg cuff (13) and a foot cuff (11) with the leg cuff having only three cells (B-D), which have a gaiter cell B adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell C adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell D adapted to wrap around the lower limb in the region between the mid-calf cell with the cells each having only one compartment (bladders B-D) for treatment of diseased leg veins.

Regarding applicant's submission that when Barak described "it is to be understood that the invention is also intended for use on any body limb such as an arm, a foot, a part of a leg, arm or foot, and may be used on two or more limbs simultaneously" the 'part of a leg' is meant to encompass the entire leg absent "the knee, the ankle, or the upper thigh" is not taken well. As discussed in the previous Office Action, a physician treats areas in need of treatment. Based on the teachings of the combined references, a skilled artisan would clearly recognize that Barak could be modified to treat a lower leg and foot without the need of the thigh region. See: figure 1 of Taheri.

Regarding applicant's argument that Barak does not teach the number of cuffs can vary, this argument is not taken well because the rejection is based on the combination of references and Taheri teaches a lower leg cuff and a foot cuff.

Applicant's arguments against the references individually one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Regarding applicant's newly added claim limitation, wherein the leg cuff consists of only three cells, each cell consisting of a single compartment, Taheri teaches a leg cuff with three cells (B, C & D) wherein each cell consists of only one compartment (bladder).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., cells in the instant application are shown as single compartments in Figure 3 and it is clear from the language already in claim 1 that each cell wraps around the limb and so is at least as large as the circumference of the limb) are not recited in the rejected claim(s). None of the claims require a cell size limitation nor do they require the cells being fully or completely wrapped around a limb. Thus, the cells disclosed by Taheri, which would at least partially wrap around a limb, meet the claimed cell limitations. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that "Barak, et al. does not suggest that it is possible to eliminate the thigh cuff and it certainly does not teach that doing so would make an effective device", applicant's attention is directed Bark's teaching in col. 10, lines 38-40, which clearly stated that "various changes, emissions to the form and detail thereof may be made therein" and thus omissions of the thigh cuff is possible, especially in view of the teaching of Taheri, as discussed above.

Applicant has not provided evidence that the Barak's device would not work effectively if the thigh cuff is eliminated. Moreover, it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the cells, when inflated, presents a smooth surface to the limb of the patient and apply an even compression to the limb) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding applicant's argument that there is no incentive to eliminate the thigh cuff of Barak to arrive at the claimed invention, the examiner respectfully disagrees for the reasons set forth in the obviousness-type rejection above.

Again, when a physician is treating a patient, they treat the part of the body in need of said treatment. Thus, if a physician was to treat a lower leg, it would be obvious to modify a leg treatment device to treat only the body part needing treatment. Since Barak discloses that "The control unit, which can be software based, controls the operation of the compressor and solenoid valves. The control unit can be programmed to achieve any desired inflating and deflating sequence and timing including delay intervals, in accordance with clinical application", a physician treating the lower leg could program the control unit to deflate and indefinitely delay inflating of the thigh portion of the device or merely modify the device to form a lower leg treatment device, taught by Taheri, to form a treatment device consisting of a leg and foot cuff.

Thus, the combined references teach the device as claimed and the incentive for modifying the device is to treat the portion of the leg in need of treatment, as determined by one having ordinary skill in the art, and since Taheri teaches a lower leg treatment devices consisting of a leg and a foot cuff, such a modification is clearly within the skill of the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771